Evaluating the Effects of Implementing a Volume-Based Protocol in an ICU setting

By

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Abstract

Background: Patients in ICUs tend to have greater protein and calorie needs than other hospital populations, especially patients who cannot eat by mouth. Meeting these needs is crucial to patient recovery, yet for many reasons, tube feeds are held. This study was conducted to evaluate the effectiveness of a volume-based (VB) enteral nutrition protocol implementation in general and medical ICUs. It is hypothesized that the volume-based method would be superior in delivering appropriate amounts of calories and protein to patients without causing undesirable side effects.

Materials and Methods: ICU patients (n=116) tolerating EN at goal for >24 hours were retrospectively reviewed in this study. Patients had EN delivered via VB (n=59) or rate-based delivery (n=57).

Results: The intervention group achieved significantly more goal calories, (SD=24.91, p=0.013), goal protein (SD=26.87, p=0.005), and goal volume of EN formula (SD=22.14, p=0.002), when compared with the control group. There was, also, a significant increase in patients who met 80% or more of their protein goal (CI 95%= 5.4% to 38.5%, p=0.011). Patients in the intervention group experienced fewer high GRV (p=0.0144) and less occurrence of diarrhea (p=0.0330). Time to reach goal rate took significantly less time in the intervention group (p=0.0198). There were no differences seen between groups for distal tube tip placement, use of promotility agents, occurrence of nausea, vomiting, constipation, malnutrition, 60-day mortality rates, or occurrence of pressure injuries.

Conclusion: Implementation of a volume-based protocol in an ICU setting has been shown to significantly improve amounts of calories and protein delivered to patients receiving enteral nutrition while not increasing the incidence of gastric residual volumes or diarrhea.

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Chapter 1: Justification

Medical professionals generally agree that enteral nutrition is necessary for many ICU patients to prevent hospital acquired malnutrition, extended patient stay, delayed recovery, and increased incidence of readmission. Because enteral nutrition has become a fixture in ICU care planning, it is important to evaluate how delivery can be optimized.

Enteral nutrition is commonly prescribed to patients to be delivered at a consistent rate over a 24-hour period. This method delivers the calories and protein that the patient needs, but not always optimally. For a myriad of reasons, delivery of enteral nutrition is held during a hospital stay, and not all reasons are considered valid by the entire care team. For example, patient diarrhea and other gastrointestinal complications are often blamed on enteral nutrition, when they may be caused by non-diet factors such as medications, patient stress, etc. Regardless, when enteral nutrition is held, the delivered volume is often significantly less than prescribed, potentially leading to underfeeding.

To address this concern, researchers have investigated volume-based delivery of enteral nutrition. Using a volume-based delivery approach, nurses account for the lapse in delivery by temporarily increasing delivery rate as guided by a table that incorporates the goal amount of formula and hours remaining (Table 1). The aim of this technique is to "catch up" milliliters of formula lost when tube feeding is held for medical procedures.

The following review of literature will present randomized control trials and quality improvement trials that observe patients in groups receiving rate-based and volume-based delivery of nutrition. Previous studies, including the "PEP-uP protocol" study and the "FEED

ME" study have shown that patients who receive the majority of their calculated calorie and protein goals are in the group receiving volume-based formula delivery. Nutrition goals, gastrointestinal distress from tube feeding and methods of delivery between institutions will also be discussed in this review. These side-effects, thought to be caused by tube feeding, are relevant within the review of literature, as they can be cause for more tube feeding holds. Additional consideration will be given to the use of hospital-wide protocols and education of clinical staff involved in prescription, selection, and administration of formula.

This purpose of this study is to evaluate the effectiveness of a volume-based enteral nutrition protocol that was conducted at the University of Kansas Health System (TUKHS) in 2017. It is hypothesized that the volume-based method would be superior in delivering appropriate amounts of calories and protein to patients without causing undesirable side effects. The data was be analyzed with hope that the evidence discovered would prove useful in expanding implementation of a volume-based protocol from the hospital's ICU, to include the medical ICU and surgical ICU. These data also add to the body of evidence for volume-based enteral nutrition protocol implementation.

Statement of Purpose:

The purpose of this investigation was to determine if volume-based delivery of enteral nutrition delivers more calories and protein, while not increasing gastric distress in ICU patients compared with traditional rate-based delivery methods.

Research Questions:

1. Does volume-based delivery of enteral nutrition deliver more calories and protein to adult ICU populations than traditional rate-based enteral nutrition delivery?

2. Does volume-based delivery of enteral nutrition cause more aspiration, ICU-acquired pneumonia, gastric residuals, vomiting, and diarrhea in adult ICU populations than rate-based enteral nutrition delivery?

3. Do patients in an ICU setting who receive volume-based delivery of enteral nutrition have decreased rates mortality and length of stay?

Chapter 2: Review of Literature

Introduction

Hospitalized patients are commonly fed through feeding tubes, when it is not an option for them to consume food orally. This practice of using enteral nutrition (EN) attenuates the stress-induced catabolism of muscle stores while aiding the patient in recovering from illness or undergoing medical procedures. Mucosal atrophy is also reversed and epithelial cell function increased when EN is initiated early, and these effects enhance immune function and decrease inflammatory response during surgical recovery (1). As a result, hospital length of stay (LOS) is shortened and hospital cost decreases. Intravenously administered parenteral nutrition, an alternative form of nutrition support, will not be included in this investigation as it provides fewer benefits to the malnourished patient and is thus used only when EN is not possible (2).

Tube feeding formulas are often prescribed by physicians, calculated to the patient's needs by a dietitian, and administered by nursing staff. This creates an environment where all staff must be aware of the delivery of patient's EN to avoid complication, such as malnutrition.

Hospital acquired malnutrition is a completely avoidable problem, yet it is still commonly occurring in many health facilities. An estimated 1/3 of hospitalized patients will become malnourished during their course of hospitalization (3). The WHO defines malnutrition as "… deficiencies, excesses or imbalances in a person's intake of energy and/or nutrients (4) Malnutrition can be debilitating and lengthen the stay of patients who were originally being treated for unrelated conditions. It is crucial for patients to receive calories and protein as close to goal as possible.

An international, prospective, observational study was conducted in 2010 to determine where gaps lie between guidelines for optimal patient care and care that is actually provided in average ICUs (1). Researchers looked specifically at surgical patients in ICU settings. In all, 5,497 patients out of a total of 269 ICUs submitted data into a secure database for analysis. Nutrition orders prescribed, actual nutrition administered, and gastrointestinal complications were documented. Age, sex, race, height, weight, and incidence of malnutrition was also analyzed. The analysis found that surgical patients in the ICU receive significantly less EN than other ICU patients, 33.4% of prescribed calories compared to 49.6% ($p = < 0.0001$). The majority of surgical patients who received the least number of calories and protein were hospitalized for gastrointestinal and cardiovascular conditions, and the study authors noted that gastrointestinal surgery was an understandable reason for the high incidence of EN delay. While the link between delayed EN initiation and cardiovascular surgery was not immediately apparent, the authors noted that hemodynamic instability could be a reason for physicians' reluctance to initiate feeds.

EN has seen some improvement in formulation in the recent past. Formulas are available in polymeric forms, which provide intact macronutrients, and in partially hydrolyzed or hydrolyzed forms, allowing for easier digestion and absorption. Many formulas exist to optimize treatment of specific conditions, such as very high protein for burn and trauma patients. While a variety of enteral nutrition products for valuable nutrition therapy exist, they are not often viewed by all practitioners as crucial to patient recovery. Research shows that EN is, however, a crucial, non-pharmaceutical, therapeutic tool (5).

Development of a protocol for administration of EN in an ICU setting creates a mutually determined standardized approach to how patient nutrition needs will be handled by all health care professionals involved. The following review of available literature looks at specific data related to complications with EN in ICU settings and administration of volume-based feeding protocols in ICU settings.

Calorie and Protein Deficits

Patients are known to lose weight during illness, and specifically muscle mass during ICU stays. In the FEED trial, Fetterplace et. al conducted a randomized clinical trial of an intervention to deliver EN through a volume-based protocol and protein supplementation in an ICU setting (6). Primary outcomes were protein and calorie delivery, measured on an average daily basis. Secondary outcomes were malnutrition, measured with a subjective global assessment; lean muscle mass, measured by change in quadriceps muscle layer thickness (QMLT); and ultrasound of muscle mass. The researchers found that in a group of sixty (n=60) patients, those receiving the intervention protocol had greater intakes of protein and calories than control (1.2 g/kg protein and 21 kcal/kg in the intervention group, compared to 0.75 g/kg protein and 18 kcal/kg in the standard care group, $p = 0.01$). The protocol group also had less incidence of malnutrition and greater measurements on average of QMLT than the control group of patients.

Situations of hypocaloric feedings are not only known to cause loss of muscle mass, but also increased incidence of nosocomial (hospital acquired) bloodstream infections (7). In a prospective cohort study, researchers reported an association between blood stream infections and failure to administer more than 25% of dietitian recommended calories. This amount is roughly ≤ 6 kcal/kg/day. Most dietitians prescribe intake amounts between 20 and 35 kcal/kg/day for patients in the ICU, as noted in other studies and recommended by A.S.P.E.N. (8).

Arabi et al were able to produce results in their 2004 study showing that a volume-based protocol was beneficial in not only meeting calorie and protein needs, but also, showing that EN is a powerful “nonpharmacologic tool”, (5). In their 203-person trial, the researchers took a 7-day EN intake average after a volume-based protocol was initiated in their intervention group. The control group received traditional rate-based EN prescribed by the care team. The results were (53.9 ± 2.3% *vs* 64.5 ± 2.2%, $p = .001$) for average calorie intake and protein intake (56.7 ± 2.6% *vs* 67.4% ± 2.7%, $p = .005$) between the intervention and control groups. Besides showing that there were dramatic increases in calories and protein delivered, excess gastric residual volumes (GRV) and diarrhea were also less frequent in the intervention group.

Gastrointestinal Complications

Common concerns about a completely liquid diet include increased frequency of diarrhea and increased risk of aspiration due to the combination of increased stomach contents in patients that are constantly reclined. Thus, GI tolerance of EN is frequently evaluated by GI output and GRV. There are two main problems with how hospitals use loose stool as a measure of EN tolerance. Firstly, there is no universal definition of diarrhea used. It may vary greatly or be up to the practitioner’s discretion to judge problematic stool consistency, volume, and frequency. Secondly, there are many factors in a hospital setting that may contribute to changes in stool characteristics. Chang et al list prescription medications, age, clinical condition, and diagnoses involving altered gastrointestinal anatomy as conditions commonly associated with change in stool characteristics, chiefly diarrhea (9). While it is accepted in practice that EN leads to less formed stools, the lack of consistent measurement criteria is where cause for concern lies.

A.S.P.E.N. recommends that dietitians monitor patient outputs and reports of diarrhea using modular products and prebiotics as deemed necessary per case (2). A.S.P.E.N also states that there are more factors, such as medications and clinical condition, that cause loose stools that are outside the dietitian's scope of practice, and therefore outside of management through EN therapy. They promote literature by Bittencourt et al that reports constipation occurring in ICU patients using EN more frequently than loose stools (10). This seems to go against trends that are seen in many ICUs included in the studies explored in this review. There is little published on using diarrhea as an indicator for intolerance of tube feeding formula. This may be due to the lack of consistency in definition.

In a 2008 study by Whelan et al, researchers looked at consistency in definition in a trial that covertly assessed nurses' ability to characterize stool (11). Nurses were provided with a chart that had categories in a range for stool output and a range for stool consistency. Over 280 days, 291 fecal samples were assessed. Stools assessed as heavy, unformed, and higher frequency were recorded in patients who were later known to have severe hypoalbuminemia, C. difficile, or receiving antibiotics ($p = 0.001$). The use of this chart showed construct validity for nurse ability to characterize stools. The author states that this type of chart will help standardize identifying stool in a clinical setting.

Ability to characterize stools is important in understanding if EN is to blame in cases of diarrhea. Since loose stools seem to frequently occur in settings where EN is being used, regardless of whether EN is the cause, it is important to be aware that the diarrhea can be modulated through use of prebiotics. Majid et al reports that prebiotics increase short-chain fatty acids and beneficial microbes in the gastrointestinal tracts of patients in an ICU (12). Antibiotics decrease the healthy microbiota of the GI where a majority of the immune system is located.

Significantly higher concentrations of bifidobacteria were identified in patients receiving prebiotic fiber. This type of supplementation would decrease the need for such frequent stool monitoring, if stool consistency can be modified.

Reignier et al, in a 2013 French ICU study, looked at whether not monitoring GRV is detrimental to ICU patient populations (13). Patients were randomized into two groups in this open-label, multi-center trial. The control group was monitored at the discretion of nursing for GRVs, as was common in the ICUs analyzed. The intervention group was monitored for vomiting and GRVs only every 6 hours and GRVs were defined as any volume greater than 250 milliliters. The proportion of ICU patients who experienced ventilator-associated pneumonia (VAP) in the consecutive 90 days was also collected. VAP is caused by stomach contents being aspirated. The risk of this occurring is thought to be linked to high GRV. In the intervention group, 16.7% of patients experienced VAP, 15.8% developed VAP in the control group. Analysis showed no significant difference between the two groups. There was also a higher proportion of patients receiving 100% of their calorie goals in the intervention group. It was determined that there was no difference in the frequency at which elevated GRV were measured between groups. This led the authors to conclude that no clinical benefit came from holding tube feeds for elevated GRV.

Other studies have come to similar conclusions about GRV. In an observational study by Padar et al, 480 patients were enrolled in an observational study in a Copenhagen medical ICU. Several important gastrointestinal symptoms were monitored by the research team that are of note. Similarly to other studies, many ICU staff members shared concerns that increased EN volume will cause increased GRVs, diarrhea, and abdominal discomfort in patients (14),(15). The researchers in the Padar article established a nurse-driven protocol with hopes to improve EN delivery while showing that gastrointestinal discomfort is independent of tube feeding practices. Their protocol incorporated an algorithm in the form of a flowsheet for making EN related decisions. They showed that use of EN increased with the use of the flowchart algorithm. The risk of patients receiving insufficient EN was significantly higher in the before group. There were no significant differences in incidence of vomiting, bowel distension, diarrhea, or large GRV (>500 mL/d) between groups, (15). The flowchart used in this study to help nursing make EN administration decisions resembled a decision-making tree used by Woien et al in a 2005 study, (16). Nurses also encouraged physicians to choose EN over PN, as EN has been shown in studies to “reduce disease by attenuating stress response”(15),(17).

Volume-Based Protocols

Because traditional EN protocols too often result in underfeeding, the potential for EN to attenuate malnutrition is theoretically reduced. Although literature on this topic is relatively recent, there is great evidence supporting the use of volume-based enteral nutrition delivery techniques in hospital ICU settings. A 2012 study by Agarwal using data from the Australasian Nutrition Care Day Study (ANCDS), analyzed information to determine if malnutrition and poor food intake (insufficient caloric intake) are independent from disease type and state (18). They reported these factors were independent from each other and that malnutrition and poor food intake is positively associated with acute care patients. The authors stress that their findings show that implementation of volume-based protocols regulating nutrition intake in ICU patients are critical to providing the best care for these patient populations.

In their observational cohort study, Alberda et al collected data from 2,772 ICU patients worldwide. Researchers found that an increase of 1,000 per day significantly reduced mortality (p=0.0014). Overall, better clinical outcomes were seen for this cohort of patients, specifically if their BMI was below 25 or above 35, which include both morbidly obese and underweight individuals; two populations most commonly seen in hospital ICUs.

With the growing evidence that accurate EN delivery is better for most patients by 2009, several landmark studies were conducted, including the "PEP-uP" and "FEEDME" trials. After iatrogenic underfeeding of ICU patients was documented in previous studies, the PEP-uP Protocol was published 2014 by Heyland, et al (19). This landmark study described the implementation of volume-based feeding in a multi-center quality improvement initiative in Canada. The PEP-uP Protocol included educational materials for physicians and nursing staff on how to administer volume-based nutrition. Options to incorporate trophic feeds and prophylactic protein or fiber supplementation were included in the PEP-uP Protocol, since they are regularly needed for patient nutrition therapy(19),(20),(14).

This study provided key details of their protocol, allowing researchers and clinicians to more easily replicate the study. The researchers who developed this protocol focused upon several key areas that are known to be critical control points for development of malnutrition for ICU patients. These key points included: 1) Early initiation of EN instead of waiting for bowel sounds was encouraged among the residents and nurses involved, as these sounds have been shown to be unnecessary markers of readiness for feeding in the GI; 2) Education on the protocol was given to all members of the medical team and reinforced as needed; 3) Independence in decision making of physicians surrounding EN; and 4)More liberal use of motility agents and protein supplements was encouraged. The PEP-uP study was funded by the makers of Peptamen and featured a focus on elemental formulas instead of the standard polymeric formulas but was otherwise conducted in a way that mirrored standard ICU care.

The PEP-uP protocol and the FEEDME protocol both involved very specific education for staff for the care teams to follow the protocols in unity. Targeted staff education is known to be important in all areas of clinical practice. Hurt, et al. looked specifically at education of physicians in a 2014 volume-based feeding trial. Patients on EN (n=121) were randomized into two groups to receive either volume-based delivery or rate-based delivery of formula (21). Residents were the targets of the nutrition education and learned to initiate feedings early in patient stays and after procedures, to avoid nil per os (NPO) time, and to count caloric deficits of their patients. Although calorie and protein needs were calculated by dietitians, implementing the practice among residents served as a tool to help the residents understand patient nutrition needs. Over all, there was a reduction in caloric deficit, shorter total LOS, shorter time spent on mechanical ventilation, and reduced amounts of infectious complication and organ failure in the volume-based group as compared to the rate-based group (21). Authors attributed these improved patient outcomes to the volume-based delivery of EN combined with resident education.

In a retrospective analysis, Khalid et al evaluated the time of EN initiation in mechanically ventilated patients on vasopressors. While all patients received EN as their sole source of nutrition, the group that received early EN (within 48 hours of admission) demonstrated lower mortality rates (34.0% to 44.0%, $p < 0.001$). The author suggested that patients who were the most ill, receiving multiple vasopressors, benefited the most from early initiation of tube feeding.

While many volume-based feeding studies are conducted in ICU settings, few have looked specifically at surgical ICUs (SICU) as a location to collect useful data. Krebs et al. studied ninety-nine (n=99) trauma and burn patients who were randomized into rate-based (control) and volume-based groups (22). Because these patients tend to have different medical needs than a cohort of standard ICU patients, they also likely have higher calorie and protein needs than their ICU counterparts. Krebs found that the group receiving volume-based nutrition had received a higher (84.5% to 73.4%, p =0.005) percentage of their total calorie goal and daily protein (86.2% vs. 77.4%; p = 0.01) intake. What is more, there were no differences in gastrointestinal distress between groups (22).

While most research on volume-based EN compared with rate-based EN has focused on calorie and protein intake, some have also evaluated differences in impacts upon patient glycemia. The perceived advantage of rate-based delivery is that, for patients with diabetes, carbohydrate intake is regulated, therefore blood glucose values will be regulated, and insulin can be regularly administered. What may not be accounted for are the stops and starts that are common with EN in the ICU. Roberts et al looked at these patterns in their 2018 study (23). Their data showed that volume-based delivery of nutrition is not associated with higher incidence of hyperglycemia (p =.67). This is an important finding since their study also reported increased delivery of calories and protein through a volume-based feeding protocol.

One study reported the impact of the registered dietitian (RD) role in monitoring the volume based EN protocol (24). This prospective interventional study was conducted in three periods: 1) Baseline initiation of a volume-based protocol, 2) Intervention without RD protocol monitoring, and 3) Intervention with an RD present to monitor the use of the protocol. As this study progressed, calorie deficits decreased. The volume-based protocol increased caloric intake of the ICU patients. When the RD was introduced, deficits decreased significantly, and protocols were followed more closely with her guidance than when other staff were solely responsible for monitoring EN.

The “Feed Early Enteral Diet Adequately for Maximum Effect” trial (FEEDME) is another landmark study in research on volume-based nutrition delivery. Based on the premise that EN “has the potential to aid in attenuating the metabolic response to stress,” that is, the ability of EN to prevent of cellular injury and modulate the immune response, researchers set out to evaluate the timing of EN (25). . The research team collected data on ICU populations of the Barnes Jewish Hospital (BJH) in St. Louis, Missouri in a 2012 quality improvement audit. This audit revealed that SICU patients were receiving 37% less than the literature recommended calorie goal of 80% for these populations. In response to these problematic numbers, BJH conducted a QI trial that implemented a volume-based protocol for all ICUs. The researchers elected RDs to educate all involved staff on how the protocol worked, so that there were no gaps in knowledge base. The results showed that the rate-based group received 63% of their total calorie goals while the volume-based group received 89% of their total goals. The authors of the published article credit the audit for this beneficial change and recommend regular and frequent audits for maintenance of best practice.

Most volume-based trials included various tools for staff to use to regulate and standardize use of EN in patients. For example, in a nurse-led intervention, a group of researchers tested an algorithm in the form of a flowchart and/or a table that attempted to implement “early and more rapid” delivery of EN in an ICU setting (16). These tools were crucial in helping nurses provide optimal EN for ICU patients.

One consistent finding among the trials was that early initiation of EN is critical for positive patient outcomes. Negative energy balances (resulting from insufficient EN delivery) were associated with more complications, especially infections and these energy balances were not able to be compensated for later in treatment, only by early initiation of EN (2, 26). To achieve early initiation of EN, protocols suggest that bowel sounds are not necessary to resume use of the GI for nutrition. Although there are some minor differences in these protocols, what is most important is providing the correct number of calories and grams of protein to the patient while preventing harm that may result from treatment.

New and innovative approaches to feed patients have demonstrated synergy between medication, nutrition, and other medical treatments. There is strong evidence that volume-based EN delivery consistently increases delivery of calories and protein without increasing gastrointestinal complications among ICU patient populations. Despite the evidence, changing practice can be slow and met with resistance. More research is needed showing that volume-based protocols in ICUs are feasible and can be reproduced.

Chapter 3: Methods

Overview & Setting

A multi-disciplinary team, led by a physician, and including nursing staff and registered dietitians, reviewed the current literature on volume-based protocols in ICU settings, including the PEP-uP protocol and FEEDME trial. A volume-based pilot study was conducted in Kansas City, Kansas in the University of Kansas Health System's MICU and ICU. The pilot study took place over a 6-week period in the Spring of 2016. After a successful pilot, a larger study was conducted in 2017, and data was collected. The analysis of data from this investigation will determine if volume-based delivery of enteral nutrition delivers more calories and protein, while not increasing gastric distress in ICU patients compared with traditional rate-based delivery methods.

A convenience sample was taken from medical ICU units 61, 63, and 65 in TUKH. Adult patients (persons >18 years of age) were recruited into the study if they were admitted into the ICU and tolerating EN for greater than 24 hours and scheduled to receive only EN for 48 hours or more. Exclusions to the study were patients on "trophic" level EN, patients fed orally, or patients receiving any parenteral nutrition. The intervention group (n=59) received EN according to the described volume-based feeding protocol. The control group (n=57) received EN that was administered in a standard rate-based delivery schedule.

Ethics

The University of Kansas Institutional Review Board (IRB) was consulted to determine if review of the QI study is necessary. This research was classified as non-human subjects research as no patient identifiers were used when data was gathered or analyzed.

Procedure

The primary outcome of this study was to determine which group of patients received more calorie and protein, and which achieved ASPEN goals of 80% calorie and protein recommendations. Secondary outcomes included: occurrence of diarrhea (defined as 5 stools or >750mL per 24-hour period), GRV measured at dangerous amounts (two consecutive GRV >250mL), ICU LOS, total LOS, 60-day mortality, and diagnosis of malnutrition. The volume goal of 250mL for GRV measurements is based off of average GRV amount seen in the intervention ICUs in the PEP-uP study, (19). Measurements for diarrhea were also based upon findings of the PEP-uP study, (19). Other data collected included patient height, weight, BMI, abdominal distention, nausea/vomiting, patient report of abdominal pain/cramping, and witnessed aspiration.

Prior to initiating the volume-based EN protocol, ICU nursing staff were educated on the volume-based protocol with materials developed by registered dietitians. Unit nurses monitored and reinforced the protocol. The nurses were provided with education reference materials including a volume-based chart that helped nurses compensate for lost hours of EN during procedure and other EN holds. A standard order for volume-based EN was also written for physicians so that EN could be initiated during the 48-hour period that dietitians have to respond to nutrition consults for tube feed orders. The parameters of the protocol are outlined in appendix B.

The data from the patients' treatment were retrieved from TUKH's electronic health records (EMR) system by the student over a 6-month period. Data collected by the student from the EMR included age, sex, weight, body mass index (BMI), hours of mechanical ventilation, hospital LOS, EN orders, volume EN received in milliliters, TF rate, hours to goal, protein and calories received, abdominal distention, nausea/vomiting, diarrhea, GRVs recorded, abdominal pain and cramping, and witnessed aspiration. These are variables listed in the primary and secondary outcomes. A full data sheet is located in Appendix A.

Data was collected from medical records created during the dates of the volume-based QI study. Patient charts were investigated to determine amounts of calories and protein delivered to study participants. Volumes of EN were collected and hours they were run for each patient. Also collected were age, height, weight, BMI, and GI symptoms. This data was organized into a format that does not disclose HIPAA protected patient information. This data was collected in a way that protected patient health information was not compromised or used in any part of the data collection process.

Analysis of Data

Data were analyzed with assistance from the Biostatistics department at KUMC to answer the research questions that are derived from the primary and secondary outcomes of the volume-based study. Independent, 1-tailed T-tests were performed to evaluate differences between groups for % goal calories, % goal protein, mean volume of formula delivered (mL), number of patients who met 80% of calorie needs, and number of patients who met 80% of protein needs. Analysis of clinical secondary outcome data were done using proportions analysis (Chi-square) to look for statistical and clinical significance between groups. This includes occurrence of nausea, vomiting, constipation, malnutrition, pressure injuries, GRVs, diarrhea, ICU LOS, total LOS, and 60-day mortality.

Chapter 4: Results

In total, 179 participants who received EN were seen in TUKHS ICUs between the study dates of March 1 and December 31, 2017. A total of 14 patients were excluded because they either did not receive TF for the minimum number of hours, or they expired prior to reaching goal rates. Time constraints limited data extraction from EMRs within the thesis project timeframe, and this led to exclusion of the remaining 21 patients for this study. However, the ordering of study participants was random, and thus the likelihood of different findings with inclusion of the excluded 21 patients is believed to be low. Thus, 116 patients tolerated EN at goal rates, and received EN for longer than 48 hours. Fifty-seven patients were randomized into the rate-based group and 59 patients were randomized into the volume-based group for the final sample. Patient characteristics of the two groups are shown in Table 1.

Table 1. Population Characteristics

	Rate-Based EN[a] (n=57)	Volume-Based EN[a] (n=59)	*P Value*
Men, (%)	57.9	55.9	.8286
Age, mean (SD)	54.5(13.5)	60.7(16.4)	.0269
Admission diagnoses (%)			
Septic shock	23.3	23.7	.9597
Respiratory failure	26.3	18.6	.3220

[a] EN = Enteral Nutrition

Primary Outcomes

The primary outcomes in this study are presented in Table 2. The intervention group achieved significantly more goal calories, (SD=24.91, p=0.013), significantly more goal protein (SD=26.87, p=0.005), and significantly more goal volume of EN formula (SD=22.14, p=0.002), when compared with the control group. The intervention group was also compared to the 80% or greater goal for calories and protein that A.S.P.E.N. recommends for optimal patient recovery, (8). There was no significant difference between groups for the proportion of patients who met 80% or higher of calorie needs (CI 95%= -7.0% to 27.5%, p=0.242). There was, however, a significant increase in patients who met 80% or more of their protein goal (CI 95%= 5.4% to 38.5%, p=0.011).

Table 2. Percent of participants achieving calorie and protein goals in Rate-based (n=57) and Volume-based (n=59) groups. **Table 2.** Primary Outcomes.

	Rate-Based EN[a] (%)	Volume-Based EN[a] (%)	*P Value*
Average goal calories	63.5	74.9	.0132
Average goal protein	60.6	75.5	.0050
Average volume in mL	54.9	67.2	.0023
Patients who met the 80% A.S.P.E.N. calorie criteria	35.1	45.8	.2427
Patients who met the 80% A.S.P.E.N. protein criteria	24.6	47.5	.0107

[a] EN = Enteral nutrition

Secondary Outcomes

Patients in the intervention group experienced fewer high GRV (p=0.0144) and less occurrence of diarrhea (p=0.0330). Time to reach EN goal rate took significantly less time in the intervention group (p=0.0198). There were no differences seen between groups for type of tube placed, use of promotility agents, nausea, vomiting, constipation, malnutrition, 60-day mortality rates, or occurrence of pressure injuries (Tables 3 and 4).

Table 3. Outcomes related to gastrointestinal tolerance of Rate-based (n=57) and Volume-based (n=59) enteral feeding protocols.

	Rate-Based (%)	Volume-Based (%)	*P Value*
GRV	28.1	10.2	.0144
Diarrhea	40.4	22.0	.0330
Nausea	26.3	22.0	.5900
Vomiting	14.0	13.6	.9504
Constipation	7.0	8.5	.7638

Table 4. Secondary Outcomes – Clinical Practice.

	Rate-Based	Volume-Based	*P Value*
G-Tube*(%)	71.9	74.6	.7436
Promotility agent use (%)	15.8	13.6	.7389
Malnutrition diagnoses (%)	19.3	27.1	.3223
Hours to goal (hrs.)	30.9	18.3	.0198
Pressure Injuries (%)	38.6	33.9	.6001
60-day mortality (%)	26.3	37.3	.2058
ICU LOS (days)	11.8	13.8	.1239
Total LOS (days)	20.1	21.9	.2859

*Compares rate of tube tip in the stomach to post-ligament of Trietz placement

Chapter 5: Discussion

This study demonstrates that a volume-based enteral nutrition protocol can increase delivery of volume, calories, and protein to critical care patients, while also reducing patient GRV and diarrhea. This quality improvement study produced results that mirror similar studies, adding to the growing body of literature that indicate volume-based protocols increase the number of calories and protein delivered to ICU patients.

In this study, patients in the volume-based EN group achieved higher overall protein goals, calorie goals, and required fewer hours to reach EN goal. Further, we found clinical significance between groups in that more patients in the VB group met greater than 80% of their total protein goal whereas no difference was seen between groups for meeting 80% of calorie goals. It is important to point out, however, that it is common practice within critical care units to permissively underfeed patients, specifically obese patients, (2).

There are several keys to success in studies evaluating the implementation of a volume-based protocol. This study was designed similar to the PEP-uP and FEED ME trials, which are known to be successful in producing improved patient outcomes. The main outcome of this study was to determine if the same findings could be replicated in this institution. As a result, the protocol was designed to factor in critical control points with each member of the care team involved, including nurses, dietitians, and physicians. The protocol itself helped to unify the actions of each member to provide optimal, evidence-based patient care.

From our results, we can see that the VB groups received superior amounts of nutrition when compared with the rate-based groups. These results are consistent with the findings of other similar studies. Results of this study also showed less incidence of high GRV and diarrhea in the VB group. While these differences between groups were statistically significant, they may not be clinically significant. It is possible that our results were skewed by the more precise use of definitions in the VB group, whereas there was no additional training for the RB group as there was no protocol change for EN delivery on that unit. As was noted in the Whelan study, giving a clear definition for GRV and diarrhea likely changed the way incidence of these symptoms was recorded (11). In contrast, many similar studies did not use a specific definition for GRV and diarrhea values. Because a higher threshold was set for both variables in the intervention group, they were likely experienced less frequently, and this also resulted in less frequency that the enteral nutrition feedings were held due to perceived GI intolerance.

An additional benefit of the study was that use of the VB protocol improved communication and cohesive patient care across professions. Standardized language in the ordering of the initial tube feeds helped unify all members of the patient care team when providing optimal nutrition for patients. The orders were written in a standardized format that not only mirrored use of a VB chart, but also the work schedule of the nurses. EN was ordered in 4-hour format as well as a 24-hour format to best fit the VB protocol into all practitioners' daily schedules.

Strengths of this study included the ability to test both protocols in a hospital setting as opposed to a lab setting. The investigators were able to record data in a real-world setting where nurses and physicians monitoring adherence to protocol were not directly involved in designing the study, reducing bias in producing study results. Our study is novel and similar to the PEP-uP studies in that we collected us of promotility agents and protein supplements in addition to the recommended EN formulas. Many studies eliminate these variables, assuming that they are confounders.

Limitations for this pilot study include small sample size and exclusion of some patients due to project time constraints. Additionally, many of the patients in this study were previously on TPN and most transitioned to oral intakes after meeting >75% of nutrition needs. This study looked only at consecutive ICU days where EN was the sole source of nutrition. However, there is clinically applicable data to be collected in the area of combined routes of feeding and how nutrition can be optimized in situations where EN and TPN are combined or where EN and PO intake are combined.

This study adds to the increasing evidence demonstrating the administration of goal volume, calorie, and protein needs is crucial to increasing patient survival rates. The results of this study show that there is potential for a volume-based EN protocol to produce less GI distress in critical care patients. This study serves to support plans for TUKHS to implement volume-based feeding protocols in their ICUs. Future research is needed to include patients with bacterial infections, blood stream infections, such as central-line associated blood stream infection (CLASBI), and incidence of Clostridium difficile as variable that may be affected by a volume-based approach.

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Appendix A

Data Collection Sheet

Data Collection Sheet

Pt Code:	Sex:	Age:

Ht:	Wt:	BMI:

Dates of ICU Admission:
Admitting Dx:

ICU Days:	Total Hospital Days:	Distal Tip Location: G/J

Enteral Nutrition Orders/Intake

EN as ordered:
Date initiated:
Kcal/Pro Goal:
Time to reach volume goal (hours):

Kcal/Pro Intake Averages							Total EN Vol (mL)
Intake Date(s):	EN Kcal	Propofol Kcal	Total	Pro (g)	Prosource (g)	Total (g)	
Total Daily AVGs:							

Promotility agents used:

Symptoms

Circle for Occurrence:	
GRV.	Diarrhea
Nausea	Vomiting
Abd pain	

Malnutrition Dx: Y/N RD/MD Date:

Pressure Injury	**Stage**	**Location**
Y/N		

60-day Mortality: Y/N

Other:

Appendix B

Protocol Parameters

Nursing Information Sheet

for Volume-Based Enteral Nutrition Protocol

- Order in 02 for volume based enteral feeding will show the total volume goal for 24 hours, as well as 4-hour goal
- 24-hour period goes from 0801 to 0800 each day.
- When day shift clears the pump at 0800, the day will start over.
- We will continue to clear our pumps every 4 hours and adjust our TF rate if necessary
    - If the patient did not receive their 4-hour goal of TF, we will adjust---see Volume ***Based Feeding*** Schedule
    - If patient received their 4-hour goal, continue TF at current rate

Example:

- The patient's order states the total volume/day=1800 mL or 300 mL every 4 hours. The hourly amount will also be listed (as it is right now) and until the patient has an interruption in tube feeding, you can use this hourly rate.
- The total volume ordered is 1800 mL the hourly amount to feed is 75 mL/hour. The patient was fed 300 mL of feeding by 1200 when you clear your pump (still chart amount given in 02)—This was at goal. Then, the tube feeding was on hold for 4 hours for procedures. At 1600, when you restart the tube feeding, the rate needs to be increased (since patient missed those 4 hours of feeding)

Volume Ordered per 24 hours – Tube feeding given so far = Volume of feeding remaining in day to feed

1800 - 300 = 1500 mL remaining to feed

- Find the current time of day on the horizontal axis of the chart, which coincides with the number of hrs. in the day remaining. For this example, the column selected would be Time of day=1600 or 16 hrs. remaining.
- Select the volume from the vertical column that is closest to the amt of feeding remaining---in this case 1500 ml
- Where the 1600/16-hour column and 1500 ml column intersects is your new TF rate. For this example, your new rate would be 94 ml/hr. Make sure to fill this rate into your

TF rate in 02 so we can track it. Also, make sure to continue to chart the volume of TF received every 4 hours when clearing the pump.

Important Nursing Assessment

- Round up to the nearest hour and rate
- Volume based feeding should be used with caution. Nursing should always assess for feeding intolerance/ Adverse Events. Examples include: abdominal distention, abdominal cramping, N/V, diarrhea (defined as 5 stools or >750 ml per 24 hr. period), 2 consecutive gastric residual >250 ml (if no other signs of intolerance).
- If the physician has ordered an IV+TF goal hourly, then adjust your IVF rate when increasing tube feeding.

Required O2 documentation for Volume Based Enteral Nutrition Pilot:

- **Record the amount of EN infused every 4 hours when pump is cleared.**
- **Record any Prosource liquid protein supplement given.**
- **Record reason for EN holds and new EN rate when restarted.**
- **Record any of the following Adverse Events:**
  - **Abdominal distention**
  - **Nausea/Vomiting**
  - **Diarrhea (defined as 5 stools or >750 ml per 24-hour period)**
  - **2 consecutive gastric residual >250 ml (if no other signs of intolerance)**
  - **Abdominal pain/cramping**
  - **Witnessed aspiration**

Appendix C

Volume-Based Delivery Chart

Volume Based Feeding Schedule

Remaining mL formula for 24 HRs

Time of day	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	00	01	02	03	04	05	06	07
HRs remaining in the day	24	23	22	21	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
2400	100	104	109	114	120	126	133	141	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2350	98	102	107	112	118	124	131	138	147	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2300	96	100	105	110	115	121	128	135	144	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2250	94	98	102	107	113	118	125	132	141	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2200	92	96	100	105	110	116	122	129	138	147	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2150	90	93	98	102	108	113	119	126	134	143	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2100	88	91	95	100	105	111	117	124	131	140	150	150	150	150	150	150	150	150	150	150	150	150	150	150
2050	85	89	93	98	103	108	114	121	128	137	146	150	150	150	150	150	150	150	150	150	150	150	150	150
2000	83	87	91	95	100	105	111	118	125	133	143	150	150	150	150	150	150	150	150	150	150	150	150	150
1950	81	85	89	93	98	103	108	115	122	130	139	150	150	150	150	150	150	150	150	150	150	150	150	150
1900	79	83	86	90	95	100	106	112	119	127	136	146	150	150	150	150	150	150	150	150	150	150	150	150
1850	77	80	84	88	93	97	103	109	116	123	132	142	150	150	150	150	150	150	150	150	150	150	150	150
1800	75	78	82	86	90	95	100	106	113	120	129	138	150	150	150	150	150	150	150	150	150	150	150	150
1750	73	76	80	83	88	92	97	103	109	117	125	135	146	150	150	150	150	150	150	150	150	150	150	150
1700	71	74	77	81	85	89	94	100	106	113	121	131	142	150	150	150	150	150	150	150	150	150	150	150
1650	69	72	75	79	83	87	92	97	103	110	118	127	138	150	150	150	150	150	150	150	150	150	150	150
1600	67	70	73	76	80	84	89	94	100	107	114	123	133	145	150	150	150	150	150	150	150	150	150	150
1550	65	67	70	74	78	82	86	91	97	103	111	119	129	141	150	150	150	150	150	150	150	150	150	150
1500	63	65	68	71	75	79	83	88	94	100	107	115	125	136	150	150	150	150	150	150	150	150	150	150
1450	60	63	66	69	73	76	81	85	91	97	104	112	121	132	145	150	150	150	150	150	150	150	150	150
1400	58	61	64	67	70	74	78	82	88	93	100	108	117	127	140	150	150	150	150	150	150	150	150	150
1350	56	59	61	64	68	71	75	79	84	90	96	104	113	123	135	150	150	150	150	150	150	150	150	150
1300	54	57	59	62	65	68	72	76	81	87	93	100	108	118	130	144	150	150	150	150	150	150	150	150
1250	52	54	57	60	63	66	69	74	78	83	89	96	104	114	125	139	150	150	150	150	150	150	150	150
1200	50	52	55	57	60	63	67	71	75	80	86	92	100	109	120	133	150	150	150	150	150	150	150	150
1150	48	50	52	55	58	61	64	68	72	77	82	88	96	105	115	128	144	150	150	150	150	150	150	150
1100	46	48	50	52	55	58	61	65	69	73	79	85	92	100	110	122	138	150	150	150	150	150	150	150
1050	44	46	48	50	53	55	58	62	66	70	75	81	88	95	105	117	131	150	150	150	150	150	150	150
1000	42	43	45	48	50	53	56	59	63	67	71	77	83	91	100	111	125	143	150	150	150	150	150	150
950	40	41	43	45	48	50	53	56	59	63	68	73	79	86	95	106	119	136	150	150	150	150	150	150
900	38	39	41	43	45	47	50	53	56	60	64	69	75	82	90	100	113	129	150	150	150	150	150	150
850	35	37	39	40	43	45	47	50	53	57	61	65	71	77	85	94	106	121	142	150	150	150	150	150
800	33	35	36	38	40	42	44	47	50	53	57	62	67	73	80	89	100	114	133	150	150	150	150	150
750	31	33	34	36	38	39	42	44	47	50	54	58	63	68	75	83	94	107	125	150	150	150	150	150
700	29	30	32	33	35	37	39	41	44	47	50	54	58	64	70	78	88	100	117	140	150	150	150	150
650	27	28	30	31	33	34	36	38	41	43	46	50	54	59	65	72	81	93	108	130	150	150	150	150
600	25	26	27	29	30	32	33	35	38	40	43	46	50	55	60	67	75	86	100	120	150	150	150	150
550	23	24	25	26	28	29	31	32	34	37	39	42	46	50	55	61	69	79	92	110	138	150	150	150
500	21	22	23	24	25	26	28	29	31	33	36	38	42	45	50	56	63	71	83	100	125	150	150	150
450	18	19	20	21	23	24	25	26	28	30	32	35	38	41	45	50	56	64	75	90	112	150	150	150
400	16	17	18	19	20	21	22	24	25	27	28	31	33	36	40	44	50	57	67	80	100	133	150	150
350	14	15	16	17	18	18	19	20	22	23	25	27	29	32	35	39	44	50	58	70	88	117	150	150
300	12	13	14	14	15	16	17	18	19	20	21	23	25	27	30	33	38	43	50	60	75	100	150	150
250	10	11	11	12	13	13	14	15	16	17	18	19	21	23	25	28	31	36	41	50	63	83	125	150
200	8	9	9	10	10	11	11	12	13	13	14	15	17	18	20	22	25	29	33	40	50	66	100	150
150	6	7	7	7	8	8	8	9	9	10	11	12	13	14	15	17	19	21	25	30	38	50	75	150